K051545

JUL 18 2005

SYBRON DENTAL SPECIALTIES

Section III - 510(k) Summary of Safety and Effectiveness

Submitter:

Sybron Dental Specialties, Inc.
1717 W. Collins Avenue
Orange, California 92867
(714) 516-7484 - Phone
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Colleen Boswell - Contact Person

Date Summary Prepared: June 2005

Device Name:

- Trade Name - L.E.Demetron II
- Common Name - L.E.D. Curing Light
- Classification Name - Ultraviolet activator for polymerization, per 21 CFR § 872.6070

Devices for Which Substantial Equivalence is Claimed:

- Kerr Corporation, *L.E. Demetron*

Device Description:

The *L.E.Demetron II* cordless curing light is a device used for the polymerization of dental materials using visible light. It consists of a cordless LED curing handpiece, a battery pack, a battery charger with built-in radiometer and a remote handpiece holder. The plastic molded handpiece contains an LED light source, a cooling fan and a digital electronic circuit consisting of surface mount components mounted on circuit boards. The handpiece functions, LED output, cooling fan, display output, curing mode selection and low battery indicators, are controlled by the digital electronic circuit and a Complex Programmable Logic Device (CPLD) chip incorporated into the control circuitry. The handpiece has a mode select button for activating the handpiece and selecting the desired curing mode. A second "trigger" button is used to activate the LED output. The handpiece is powered by a removable 4 cell, low voltage, Ni-MH battery pack. A molded plastic, triangular enclosure houses a printed circuit board with control circuitry for the battery charging function and the LED curing radiometer.

Intended Use of the Device:

The intended use of *L.E.Demetron II* is for the polymerization of visible light cured materials.

Substantial Equivalence:

The *L.E.Demetron II* is substantially equivalent to other legally marketed devices in the United States. The *L.E.Demetron II* functions in a manner similar to and is intended for the same use as the *L.E. Demetron* designed by Kerr Corporation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 1 8 2005

Ms. Colleen Boswell
Director, Corporate Compliance
Sybron Dental Specialties, Incorporated
1717 West Collins Avenue
Orange, California 92867

Re: K051545
Trade/Device Name: L.E. Demetron II
Regulation Number: 21 CFR 872.6070
Regulation Name: Ultraviolet Activator for Polymerization
Regulatory Class: II
Product Code: EBZ
Dated: June 08, 2005
Received: June 10, 2005

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu S. Lin, PhD
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051545

Device Name: *L.E.Demetron II*

Indications for Use:

The *L.E.Demetron II* is an L.E.D. visible light curing unit intended for polymerization of light cure materials by dental professionals.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert S Beth DDS for Dr. Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K051545